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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/531,870

04/19/2005

Tanel Ténson

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EXAMINER

VOGEL, NANCY S

ART UNIT

PAPER NUMBER

1636

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/531,870		TENSON ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Nancy T. Vogel		1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 25-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 37-42 is/are allowed.
- 6) ☒ Claim(s) 25-36 and 43-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>7/14/05</u> . | 6) <input type="checkbox"/> Other: ____.  |

### **DETAILED ACTION**

Claims 25-46 are pending in the case.

Receipt of the Information Disclosure Statement on 7/14/05 is acknowledged.

#### ***Sequence compliance***

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because sequences are set forth in the drawings that lack sequence identifiers. It is often convenient to identify sequences in figures by amending the Brief Description of the Drawings section (see MPEP 244.02). If the sequences are already present in the sequence listing, it would be remedial to amend the Brief Description of the Drawings to include the appropriate sequence identifiers. Applicants are required to comply with all of the requirements of 37 CFR 1.821 - 1.825. Any response to this office action that fails to meet all of these requirements will be considered non-responsive. The nature of the noncompliance with the requirements of 37 C.F. R. 1.821 through 1.825 did not preclude the examination of the application on the merits, the results of which are communicated below.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25-36, 43-46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejection is based on the Guidelines for the Examination of Patent Applications under the 35 U.S.C. 112, first paragraph "Written Description published in the Federal Register (Volume 66, Number 4, Pages 1099-1111). Claims 25-46 are drawn to a selection system comprising a bacterial cell deficient of araD gene into which a vector carrying an araD gene or a catalytically active fragment thereof has been added; a vector comprising a mutated araD gene, or a catalytically active fragment thereof; a method of selecting cells transformed with a plasmid containing an araD gene or a catalytically active fragment thereof; dependent claims also recite that the araD gene is mutated. Claims 25-36 and 43-46 are genus claims in terms of a selection system using, a vector comprising, or method of selecting cells transformed with a plasmid containing: any catalytic fragment of the araD gene (presumably the protein encoded by the gene is intended), or any mutated araD gene, or any araD gene, including catalytically active fragments and mutants thereof, from any organism. Furthermore, claim 33 is a genus claim in terms of a DNA sequence encoding any nuclear-anchoring protein, which comprises any DNA binding domain which binds to a specific DNA sequence and any function domain that binds to a nuclear component, or

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any functional equivalent thereof, and any multimerized DNA sequence forming a binding site for said nuclear-anchoring protein. The claims encompass a broad class of vectors, systems or methods that comprise or use any araD gene encoding any catalytic fragment, or any mutated araD, which provides selective ability, or any DNA encoding any nuclear-anchoring protein, any DNA binding domain, and any multimerized DNA sequence forming a binding sequence for any nuclear-anchoring protein. While the specification provides general information on the araD gene of E. coli, there is no disclosure of the precise amino acids which are necessary for catalytic activity. Furthermore, there is no disclosure of the precise amino acids which are necessary for catalytic activity from any araD from different organisms. Furthermore, although the specification discloses a mutated araD gene from E. coli that has a stop codon at codon 8, that functions to encode enough araD encoded protein to allow growth of a cell having a deletion of the araD gene, (which is proposed to be the result of read-through of the stop codon in sufficient amounts to produce the araD protein for growth on arabinose), there is no disclosure of any other mutation events in the araD gene which have the same effect, or araD genes from other organisms which when mutated to produce a stop codon, would have the same effect. The disclosure is not deemed to be descriptive of the complete structure of a representative number of species encompassed by the claims as one of skill in the art cannot envision all the encompassed catalytic active araD protein fragments, or mutated araD, or proteins that have DNA binding domains and functional domains that bind to a nuclear component, or multimerized DNA sequence forming binding site for said protein, based on the

teachings of the specification. It is noted that in order to provide a selective marker, enough functional araD encoded protein must be produced or expressed in order to complement the deletion or elimination of functional araD encoded protein provided by the host cell. Furthermore, it is noted that the araD may be from any organism, and therefore the recitation of "position 8" may be occur at different structural regions in different araD molecules, and may not result in a functional polypeptide when expressed. Therefore, the specification does not described the claimed selection system , vector and method using said vector, in such full, clear, concise and exact terms so as to indicate that Applicant had possession of the method at the time of filing the present application. Thus, the written description requirement has not been satisfied.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25-36, 43-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 25, 32-34, 43 and by dependence claims 26-31, 35, 36, 44-46 are vague and indefinite in the recitation of "an araD gene, or a catalytically active fragment thereof", since genes are not generally considered to be catalytically active (or inactive). Presumably, the encoded polypeptide or enzyme is intended.

Furthermore, claim 27, and by dependence claim 28 are vague and indefinite in the recitation of "said araD gene", since the claim on which the claims depend, claim 25, recites two araD genes, and it is not clear which is intended.

Furthermore, claim 36 is vague and indefinite in the recitation of "a mutation in Shine-Dalgarno sequence", since it is not clear what Shine Dalgarno sequence is intended, and since there is no recitation of a Shine-Dalgarno sequence in the claim on which the claim depends, i.e. claim 34.

### ***Conclusion***

Claims 37-42 are allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy T. Vogel whose telephone number is (571) 272-0780. The examiner can normally be reached on 7:00 - 3:30, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NV  
4/29/07

  
NANCY VOGEL  
PRIMARY EXAMINER